



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Pat nt and Trad mark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/628,345 07/28/00 CAVAZZA

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EXAMINER

KIM, J

ART UNIT

PAPER NUMBER

1617

5

DATE MAILED:

01/12/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.

09/628,345

Applicant(s)

CAVAZZA, CLAUDIO

Examiner

Jennifer M Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 8 and 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.

- 17) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: \_\_\_\_\_.

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#### DETAILED ACTION

1. Applicant's election of the combination of propionyl L-carnitine and simvastatin in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that item 1 of the Official Action is not an election of species requirement, rather it is restriction requirement. The claims are drawn to a synergistic effect that unrelated combinations of compounds yielding synergistic effects, which are inherently unpredictable and are hence capable of supporting separate and distinct patents.

The claims have been examined only to the obviousness of administering the elected active agents to achieve the claimed effect.

Claims 1-4, 8, and 12-14 are withdrawn from consideration.

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### ***Specification***

The specification is objected to because of the following informalities: The section heading is missing. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admission.

Applicant admits at page 2, lines 11-20 that the statins including simvastatin reduce the hepatic synthesis of cholesterol.

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Applicant also admits at page 3, line 22 through page 4, line 1, that the antitriglyceridaemic and anticholesterolameic effect of a number of **alkanoyl** carnitines are well known.

The claims differ from the cited references in claiming combination of alkanoyl carnitine such as propionyl L-carnitine and simvastatin to treat disorders associated with abnormal lipid metabolism. To incorporate propionyl L-carnitine with simvastatin to treat disorders associated with abnormal lipid metabolism would have been obvious because the antitriglyceridaemic and anticholesterolameic effect of a number of **alkanoyl** carnitines are well known. It would be expected that the combination of any **alkanoyl** carnitines with simvastatin components would lower lipid conditions as well.

The skilled artist would have been motivated to combine above active agents with reasonable expectation of success to treat disorders associated with abnormal lipid metabolism.

Thus, the claims fail to patentably distingusih over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

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None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is (703) 308-2232. The examiner can normally be reached on Monday through Friday from 9 AM. to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Theodore J. Criares  
Primary Examiner  
Art Unit 1617

jmk  
January 8, 2001